II. Remarks and Arguments:

Claims 1-7, 9-10, 14-16, and 18-30 are pending. Claim 29 has been amended. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

A. Claim Objection:

In the Office Action, the Examiner objected to claim 29 for depending from a cancelled claim. Claim 29 has been amended to depend from claim 14. Accordingly, claim 29 no longer depends from a cancelled claim. Therefore, Applicants respectfully request that the Examiner's objection be removed.

B. Rejection Under 35 U.S.C. § 103(a):

In the Office Action, the Examiner rejected claims 1-7, 9, 10, 14-16 and 18-30 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,128,143 to Baichwal et. al. (hereinafter "the '143 patent") in view of U.S. Patent No. 5,472,712 to Oshlack et. al. (hereinafter "the '712 patent") and in further view of U.S. Patent No. 4,939,177 to Colombo (hereinafter "the '177 patent"). The Examiner stated that:

> "Baichwal discloses sustained release excipient and tablet formulation comprised of xanthan gum and locust bean gum (within the ratio specified by applicants), a moisturizing agent (obviously the same as wetting agent), several inert diluents and a medicament (ratio of gelling agent and medicament are within the ranges specified by applicant)"

The Examiner admitted that the '143 patent does not teach a "solid support", therefore, the Examiner relied on the '712 patent for its purported teaching of a solid support ("The limitation of applying a solid support to the tablet is met because the coating of ethylcellulose in the Oshlack patent obviously gives support to the physical shape and hardness of the tablet,...."). The Examiner also relied on the '177 patent for its teaching of ethyl cellulose as a support platform ("Columbo discloses the support thickness within the ranges claimed by applicant; [and] all the methods claimed by applicant to apply it unto the surface (spray drying, immersion and compression coating).

Independent claim 1 of the present invention recites:

> 1. A method of preparing a bioavailable sustained release tablet comprising:
>
> combining (i) a medicament in amorphous form, (ii) a wetting agent and (iii) a sustained release excipient to obtain a mixture; said sustained release excipient comprising a gelling agent, an ionizable gel strength enhancing agent, and an inert diluent, the ratio of inert diluent to gelling agent being from about 1:8 to about 8:1, said ionizable gel strength enhancing agent increasing the gel strength of a gel formed when said solid dosage form is exposed to environmental fluid, and said gelling agent comprising xanthan gum and locust bean gum in a ratio of from about 1:3 to about 3:1;
>
> thereafter drying and milling said mixture to obtain a sustained release tablet; applying a support platform to said tablet; and
>
> forming said sustained release product into orally administrable unit doses.

As indicated by the Examiner, the '143 patent does not teach or suggest a solid support. Furthermore, the '143 patent also does not teach or suggest the use of a medicament in amorphous form as claimed in the present invention.

Applicant respectfully submits that the teachings of the '143 patent are not properly combinable with the teachings of the '712 patent. The '143 patent is directed to a free-flowing directly compressible sustained release excipient and a tablet formulation comprising the sustained release excipient and an active agent. The tablet formulations described in the '143 patent are prepared by mixing together the desired amounts of sustained release excipient, active agent and optional ingredients (e.g., lubricants) and tableting the mixture using conventional tableting techniques. In contrast, the '712 patent is directed to controlled release substrates, wherein an active agent substrate(s) (e.g., tablet, spheroid (bead), microsphere, seed, pellet, or other multi-particulate system) is/are coated with an aqueous dispersion of a hydrophobic polymer, e.g., ethylcellulose, wherein the controlled release is caused by a coating of the substrate with the hydrophobic polymer (See: '712 patent at col. 3, lines 24-27) and not by mixing together the active agent and a sustained release excipient and tableting the mixture into tablets as disclosed in the '143 patent. There is no motivation provided by the '712 patent that

would suggest to one skilled in the art to combine the teachings of a patent directed to coated substrates (e.g., the '712 patent) to cure the deficiencies of a patent that is directed to a tablet formulation comprising a mixture of a sustained release excipient and an active agent (e.g., the '143 patent).

Even if motivation were proved to one skilled in the art to combine the teachings of the '712 patent with the '143 patent, the result would not be the dosage forms claimed in the present invention, but instead would be a dosage form comprising active agent substrates coated with a controlled release coating comprising an sustained release excipient comprising a gelling agent, an ionizable gel strength enhancing agent, and an inert diluent.

With regard to the '177 patent, the Examiner asserted that the '177 patent "is used primarily to show that ethylcellulose as a support platform and the method to apply it was well known in the art." Applicant acknowledges that the '177 patent and its teaching of a support platform was known in the art. In fact, Applicants specifically referred to and incorporated by reference the teachings of the '177 patent in the specification of the present invention (See: page 19, line 24 to page 20, line 9) for its teaching of a support platform. While Applicant had the foresight to add a support platform to the tablet formulations described in the present invention and incorporated the teachings of the '177 patent to provide written description for such a support platform, Applicant respectfully submits that no motivation was provided by the teachings of the '177 patent to do so. Accordingly, independent claim 1 and the claims that depend there from are not obvious over the '143 patent in view of the '712 patent in further view of the '177 patent.

In view of the arguments provided above, it is respectfully submitted that claims 1-7, 9, 10, 14-16 and 18-30 of the present invention are not obvious over the '143 patent in view of the '712 and '177 patents. Therefore, the Examiner's rejection should be removed.

C. **Double Patenting Rejection:**

In the Office Action, the Examiner rejected claims 1-7, 9, and 10, 14-16 and 18-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. 6,048,548 in view of U.S. 4,839,177.

The Examiner also rejected claims 1-7, 9, 10, 14-16 and 18-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. 6,709,677 in view of U.S. 4,829,177 (Columbo).

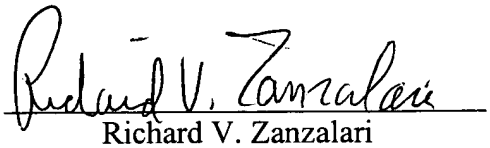
Applicants respectfully submit that upon receipt of a Notice of Allowance indicating the present claims are otherwise allowable, the filing of a terminal disclaimer will be considered.

III. CONCLUSION:

Applicants respectfully submit that in view of the arguments made, the pending claims are in condition for allowance. An early and favorable action on the merits is earnestly solicited.

No fee is believed due. If it is determined that any fees are due, the Commissioner for Patents is hereby authorized to charge said fees to Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
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